JOSEPH H. HUNT
Assistant Attorney General
DAVID M. MORRELL
Deputy Assistant Attorney General
GUSTAV W. EYLER
Director
Consumer Protection Branch
NATALIE N. SANDERS
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
450 5th Street, NW, Suite 6400-South
Washington, D.C. 20530
Telephone: (202) 598-2208
Facsimile: (202) 514-8742
E-mail: Natalie.N.Sanders@usdoj.gov

Attorneys for Plaintiff
UNITED STATES OF AMERICA

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. CALIFORNIA STEM CELL TREATMENT CENTER, INC., *et al.* Defendants.	No. 5:18-CV-01005-JBG-KKx Hon. Jesus G. Bernal Riverside, Courtroom 1 **[PROPOSED] JUDGMENT GRANTING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND GRANTING PERMANENT INJUNCTIVE RELIEF**

This matter came on regularly for hearing before the Court on Plaintiff United States of America's Motion for Summary Judgment filed on July 8, 2019. The Court, having considered all papers in support of and in opposition to the Motion, as well as arguments

of counsel, being fully advised and good cause appearing, therefore rules and orders as follows:

IT IS HEREBY ORDERED THAT Plaintiff's Motion for Summary Judgment is GRANTED on the grounds that there exist no triable issues of disputed material facts, and that Plaintiff United States of America is entitled to judgment as a matter of law.

The Court has jurisdiction over the parties and the subject matter of this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345; venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), a "drug" includes any article that is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," 21 U.S.C. § 321(g)(1)(B), or that is "intended to affect the structure or any function of the body," 21 U.S.C. § 321(g)(1)(C).

Defendants manufacture or have manufactured three adipose-derived stromal vascular fraction ("SVF") products: (1) an SVF product, (2) a product that combines SVF and Vaccinia Vaccine, Live, and (3) an expanded SVF product (collectively, the "CSCTC products").

The CSCTC products are "drugs" within the meaning of the FDCA, 21 U.S.C. § 321(g)(1)(B) and (C), because Defendants' records, public statements, and information contained on Defendants' websites and elsewhere establish that CSCTC products are intended to be used in the cure, mitigation, or treatment of diseases in man and/or to affect the structure and function of the body.

The CSCTC products are "prescription drugs" within the meaning of 21 U.S.C. § 353(b)(1)(A) because, due to their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary to their use, they are not safe for use except under the supervision of a practitioner licensed by law to administer such drug.

The CSCTC products are "new drugs" within the meaning of 21 U.S.C. § 321(p)(1), because they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for

use under the conditions prescribed, recommended, or suggested in their labeling. The CSCTC products are also "new drugs" within the meaning of 21 U.S.C. § 321(p)(2), because they have not been used to a material extent or for a material time under the conditions prescribed, recommended, or suggested in their labeling.

The CSCTC products are "human cells, tissues, or cellular or tissue-based products" ("HCT/Ps"), which are defined as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient." 21 C.F.R. § 1271.3(d).

Because the CSCTC products do not meet all of the criteria in 21 C.F.R. § 1271.10(a), and do not fall within any of the exceptions in 21 C.F.R. § 1271.15, the CSCTC products are regulated as drugs and biological products under the FDCA and section 351 of the Public Health Service Act ("PHSA"), and are subject to the provisions of the FDCA and the PHSA, including the FDCA's adulteration, misbranding, and premarket approval requirements. 21 C.F.R. § 1271.20.

Because Defendants do not manufacture the CSCTC products in a manner that conforms to CGMP, the CSCTC products are adulterated within the meaning of the FDCA, 21 U.S.C. § 351(a)(2)(B).

The CSCTC products are misbranded within the meaning of the FDCA, 21 U.S.C. § 352(f)(1), because they are drugs and their labeling fails to bear adequate directions for use, and because they are not exempt from the requirements of 21 U.S.C. § 352(f)(1).

The CSCTC products are misbranded within the meaning of the FDCA, 21 U.S.C. § 353(b)(4) because they are prescription drugs and, at times prior to dispensing, their labels fail to bear, at a minimum, the symbol "Rx only."

Defendants' SVF/Vaccinia product is misbranded within the meaning of the FDCA, 21 U.S.C. § 352(j), because it is "dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."

Defendants violate 21 U.S.C. § 331(k) by causing the adulteration of CSCTC

products within the meaning of 21 U.S.C. § 351(a)(2)(B), while they are held for sale after shipment of one or more of their components in interstate commerce.

Defendants violate 21 U.S.C. § 331(k) by causing the misbranding of CSCTC products within the meaning of 21 U.S.C. §§ 352(f)(1), 352(j), and 353(b)(4), while they are held for sale after shipment of one or more of their components in interstate commerce.

Defendants CSCTC, Berman, and Lander violate 21 U.S.C. § 331(c) by receiving drugs that are misbranded within the meaning of 21 U.S.C. §§ 352(f)(1) and 353(b)(4) in interstate commerce and delivering or proffering for delivery such drugs for pay or otherwise.

Under 21 U.S.C. § 332(a), district courts have jurisdiction to enjoin violations of the FDCA. *United States v. Organic Pastures Dairy Co.*, 708 F. Supp. 2d 1005, 1011 (E.D. Cal. 2010). The FDCA's injunctive power should be exercised in light of its purpose to protect the public health, *see United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969), and is appropriate when the United States establishes that the defendant has violated the applicable statute and that there exists "some cognizable danger of recurrent violation." *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953); *United States v. Rhody Dairy*, 812 F. Supp.2d 1239, 1245-46 (W.D. Wash. 2011).

The probability of future violations may be inferred from past unlawful conduct. *See United States v. Laerdal Mfg. Corp.*, 73 F.3d 852, 857 (9th Cir. 1995) (*citing S.E.C. v. Koracorp Indus., Inc.*, 575 F.2d 692, 698 (9th Cir. 1978)); *United States v. Odessa Union Warehouse Coop*, 833 F.2d 172, 176 (9th Cir. 1987); *Organic Pastures*, 708 F. Supp. 2d at 1012.

Plaintiff, the United States of America, is entitled to judgment as a matter of law because the undisputed evidence shows that Defendants have repeatedly violated (a) 21 U.S.C. §§ 331(k) & (c), by causing the adulteration and misbranding of drugs while holding them for sale after shipment of one or more of their components in interstate commerce, and (b) 21 U.S.C. § 331(c), by receiving misbranded drugs in interstate commerce and delivering or proffering for delivery such drugs for pay or otherwise. Based

on these undisputed, repeated violations, there is a reasonable expectation that Defendants will continue to violate the FDCA in the future if not enjoined.

IT IS THEREFORE FURTHER ORDERED THAT Plaintiff's request for permanent injunctive relief is GRANTED against Defendants California Stem Cell Treatment Center, Inc., Cell Surgical Network Corporation, Elliot B. Lander, M.D., and Mark Berman, M.D. The Court's order of permanent injunction will be entered separately.

IT IS FURTHER ORDERED THAT this case is CLOSED for administrative purposes. All hearings are CANCELLED; all deadlines are VACATED; and all other pending motions, if any, are DENIED AS MOOT.

//

//

//

SO ORDERED:

Dated this _____ day of _____, 2019.

_____
Hon. Jesus G. Bernal
UNITED STATES DISTRICT JUDGE